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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/441,875	11/17/1999	DAVID E. CHARLTON	CWP-012CN3	5134

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EXAMINER

DO, PENSEE T

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 12/10/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/441,875

Applicant(s)

CHARLTON ET AL.

Examiner

Pensee T. Do

Art Unit

1641

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 September 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): obvious-type double patenting.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 27-39.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: see attachment

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ADVISORY ACTION

Amendment Entry

1. The after-final amendment filed on September 20, 2001 has been entered.

Withdrawn Rejections

2. The obvious-type double patenting rejection is withdrawn herein.

MAINTAINED REJECTION

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 27-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown, III et al. (EP 217 403 A2).

Brown has a test device (10) comprising a casing (14) defining a sample inlet and viewing window (fluid chamber 7) and having disposed therein a test strip comprising a porous fiber matrix 12 (equates the sorbent material which defines a flow path for transporting the liquid sample therealong from a sample contact region to a test site and a control site) and a test site (34) comprising an immobilized first protein to a ligand, and a control site (32) comprising immobilized second protein (i.e. an immobilized binder which binds to the conjugate, which conjugate binds to the ligand), and a filter means (22), which device is useful for competitive,

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sandwich and indirect assays. Chorionic gonadotropin is an explicitly illustrated ligand (example 3). Particles coated with first protein are immobilized within the porous fiber matrix 12 (see col. 4, line 49-col. 5, line 2). The first protein and second protein consists of a variety of monoclonal antibodies or polyclonal antibodies. (See col. 5, lines 54-56). The sorbent means 20 disposed in the casing 14 is for absorbing excess fluid during the use of the assay device. The absorbent means 20 comprises one or more layers of material and is in physical contact with the barrier material 18, when used, or with the reaction matrix 12. (See col. 10, lines 29-46).

Response to Arguments

5. Applicant's arguments filed September 20, 2001 have been fully considered but they are not persuasive.

Regarding the 102(b) rejection by Brown, III et al. for claims 14-26, applicant submits that the invention is directed to a test device which comprises a test strip (defined as a long, narrow piece of material) and the test strip comprises a sorbent material that permits lateral flow from a sample contact region to a test site and a control site. Applicant argues that Brown fails to teach a test strip as a long, narrow piece of material which permits lateral flow from the sample contact region to a test site and a control site. Applicant also argues that Brown fails to disclose colored particulate material.

A test strip, regardless of size and shape, has one unique function, that is to transport materials such as fluid sample. Since Brown's disk-shaped test strip performs the same function, it inherently reads on the test strip of the invention. Furthermore, applicant fails to describe the

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specific shape of the claimed test strip in the specification. One skilled in the art would be able to vary the size and shape of the test strip according to his/her preference without alternating the functions of the test strip. The sorbent material of Brown does not equate the sorbent material of the invention. Rather, the porous fiber reaction matrix is the claimed sorbent material. Responding to the argument that Brown lacks the teaching of lateral flow, Brown teaches that particles coated with first protein and immobilized second protein are on the reaction matrix. Inherently, the test site and the control site must be in lateral flow communication. Regarding the argument about the colored particles, since Brown teaches a viewing window and particulate labels (particles coated with first protein), the reference inherently reads on colored particles as being used as labels for the assay.

Applicant also argues that the device of Brown III does not allow automatic assays to be carried out. Instead, Brown III envisions other formats, all require multiple sequential manipulative steps.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., automatic assay performance) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims of the invention does not exclude manipulative steps. Furthermore, the claims are drawn to a device, not a method.

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Applicant also submits that Brown III fails to teach a conjugate comprising a colored particulate material which produces at the test site "color visible to the unaided eye". No substrate addition is necessary to develop color.

Since the claims contain an opening language, they fails to exclude any additional materials such as a substrate to develop "color to the unaided eye".

Applicant also submits that Brown III fails to disclose "conjugate comprising the colored particulate material that moves along the flow path".

Brown III teaches that a second labeled reagent which can be bound to the analyte which is bound by the reagent retained within the matrix and that the label of the second reagent produces detectable response which is indicative of the presence and/or amount of the analyte. Such a detectable response can be read visually and can advantageously be a color response. (see col. 4, lines 4-19). Obviously, the second label reagent moves free along the flow path to bind to the analyte that has been bound to the immobilized particles.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is (703) 308-4398. The examiner can normally be reached on Mon-Fri. from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ /641

Pensee T. Do
Patent Examiner
December 3, 2001